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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,229	10/17/2003	Douglas N. Hess	P-11127.00	9463

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MEDTRONIC, INC.
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EXAMINER

ROBERTS, DARIN

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/688,229	Applicant(s) HESS ET AL.	
	Examiner Darin R. Roberts	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-18 is/are rejected.
- 7) ☒ Claim(s) 6-8 and 19-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/22/2005</u> <u>and</u> <u>8/05/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 8 & 12-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Min et al. (US 6937897 B2).

In reference to **claim 1 & 5**, the Min et al. patent teaches an implantable medical device (see abstract), comprising; an elongated body including a lumen and an elongated member extending within the lumen (see fig. 3 & column 3, lines 9-13), a distal tip coupled to the body and including a canted passageway extending distally from the lumen of the body and an opening terminating the passageway and positioned in proximity to a distal end of the distal tip (see fig. 3, & fig. 5B). the Min et al. patent

also teaches a helical fixation element coupled to the elongated member and adapted to deflect along the canted passageway of the distal tip (see column 4, lead lines 62-64 & fig. 1) wherein the elongated member is adapted to move the helical element through the passageway of the distal tip and out the opening and to rotate the helical element thereby affixing the helical element into an implant site (see fig. 1 & fig. 3 & column 5, lead lines 47-61).

In reference to **claim 2**, the Min et al. patent teaches a device of claim 1, wherein the helical fixation element deflects by means of a flexible coupling with the elongated member (fig.3).

In reference to **claim 3**, the Min et al. patent teaches a device wherein the flexible coupling is referred to as a conductor (se fig. 3)

In reference to **claim 4**, the conductor coil of fig. 3 can be described as a spring that acts as a coupling device.

In reference to **claim 12**, the Min et al. patent teaches a medical device wherein the elongated member comprises a conductor and the helical fixation element comprises an electrode see (fig. 5B).

In reference to **claim 13**, the Min et al. patent teaches a medical device wherein the body further includes an elongated conductor extending therein and the distal tip further includes an electrode coupled to the conductor (see fig. 3 & column 5, lead lines 47-61).

In reference *to claims 14 & 15*, the Min et al. patent teaches a medical device wherein the electrode is positioned adjacent to and distal as well as proximal to the opening of the distal tip (see fig. 1 & fig. 3).

In reference to *claims 16*, the Min et al. patent teaches a medical device wherein the distal tip of the further includes an asymmetrical radial section facilitating orientation of the opening of the distal tip toward the implant site, because the right branch of the figure 7 embodiment teaches an asymmetrical radial section facilitating orientation of the opening of the distal tip and it directs the distal tip toward the implant site (see fig. 7).

In reference to *claims 17*, the Min et al. patent teaches a medical device of wherein the distal end of the asymmetrical radial section takes on the shape of a tubular bell (see fig. 7).

In reference to *claims 18*, the Min et al. patent teaches a medical device wherein the elongated body includes a curved distal portion in proximity to the coupling with the distal tip, the curved distal portion facilitating orientation of the opening of the distal tip toward the implant site (see fig. 7 & fig. 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Min et al. (US 6937897 B2).

In reference to **claim 9-11**, Min et al. discloses the invention substantially as claimed, however lacks a teaching of the helical element being of a platinum-iridium alloy, a super elastic metal, or a synthetic resin, however, it is known in the art for one to use such materials for making fixation elements, therefore, absent any teaching of criticality or unexpected result, it would have been obvious to one of ordinary skill in the art to employ any durable, biocompatible material capable of fixating the lead to the desired location, in place of the Min et al. fixation helix material as a mere choice in engineering design.

Allowable Subject Matter

Claims 6-8 & 19-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Bonner (US 5609621 A), Gold (US 446375 A), and Wittkampf (US 4136703 A) patents are all being cited because each teaches an implantable lead possessing a helical fixation element and a distal end that is either curved or capable of being curved.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571) 272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

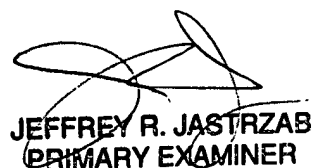
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-9900.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Darin R. Roberts
Patent Examiner
Art Unit 3762

D. R.


JEFFREY R. JASTRZAB
PRIMARY EXAMINER

2/4/14